

Message

From: Ian Murphy [ian.murphy@bayer.com]
Sent: 4/28/2021 5:17:47 PM
To: Crawford, Lydia [Crawford.Lydia@epa.gov]
CC: Schmid, Emily [Schmid.Emily@epa.gov]
Subject: RE: Status on pending 71995-AG/71995-63
Attachments: 71995-63_Roundup Landscape Weed Preventer_04282021.pdf; 71995-63_Roundup Landscape Weed Preventer_Highlighted_04282021.pdf

Here is the update label, both a base and a highlighted version. The Physical/Chemical Hazard statement appears on page 2.

Ian Murphy
Federal Registrations Manager

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Wednesday, April 28, 2021 9:44 AM
To: Ian Murphy <ian.murphy@bayer.com>
Cc: Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Hi Ian,

The only think missing is that physical/chemical hazards statement from the label. I know we're right up against the deadline and that's a challenge. Do you think you can submit the label to me today with that change or do we need to renegotiate for more time?

Best,
Lydia

From: Crawford, Lydia
Sent: Tuesday, April 27, 2021 4:14 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG/71995-63

You don't need to submit updated CSFs with the reg number, we mark it on our copies that go in the file. I've spoken to the chemistry reviewer, and there is a chemical physical hazards statement that needs to be added to the label. Please add the following to the label and send it back to me, then we I think we can still meet the PRIA date:

"Physical/Chemical Hazards: Do not use with or store near any oxidizing or reducing agents"

Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Tuesday, April 27, 2021 3:10 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Okay, sounds like progress is being made. Thanks. Does that tell you/us anything on potential completion timing?

BTW: should I send in updated CSFs that have the correct EPA reg # in them? Do registrants do that after a new product is accepted like they do with sending in the final printed label, or should I try to get in before? I don't want to delay anything, though, and maybe it is less important for this as it is confidential info.

Ian

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Tuesday, April 27, 2021 2:38 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG/71995-63

Hi Ian,
It's currently in secondary review.
Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Tuesday, April 27, 2021 2:20 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Lydia, any word from the chemistry review?

Ian

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Monday, April 19, 2021 4:33 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG/71995-63

Ian,
No that's fine. Please keep it as other ingredients.
Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Thursday, April 15, 2021 3:44 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Lydia,

I am glad to get that agreement from the toxicologists. I attach labels with all the other requests from Tuesday.

Our organization went through an effort many years ago to update our labels away from "inert ingredients" to "other ingredients" based on EPA requests (and guidance), so interesting/surprising to see it go the other way.

Per the LRM (chpt 5, section II.A.1) either are acceptable. It also notes that PRN 97-6 states "Other Ingredieints" is preferred for consumer products like this.

- I. From PRN 97-6:
- II. In 1996, EPA began a Consumer Labeling Initiative (CLI), which has as its goal the **improvement of consumer labeling** (focusing on pesticide products). ...interviews demonstrated that many consumers have a misleading impression of the term "inert ingredient," believing it to indicate water or other harmless ingredients.

A number of comments from the public and the consumer interviews **recommended that EPA discontinue the use of the term. By this notice, EPA is implementing that recommendation with respect to pesticide labeling**....Effective immediately, **EPA** will permit (and **encourages**) **registrants and applicants for registration to substitute the more neutral term "Other ingredients"** on their pesticide labels

Is there guidance that has changed, or could we keep "Other"? This would keep this product aligned with our other consumer products and the guidance that I am aware of.

Ian

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Thursday, April 15, 2021 9:43 AM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG/71995-63

Good morning Ian,

After reviewing everything with our toxicologists, the Agency will accept your rebuttal to not include the PPE language. Though to be clear, chapter 10 of the LRM defers to the toxicology assessment when determining PPE.

The statement "For [outdoor] residential use [only]" is also acceptable and encouraged for residential uses. I did notice that the ingredients statement says "other ingredients", and the agency requests that you change that to "inert ingredients" on pg 1.

Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Wednesday, April 14, 2021 1:21 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Lydia,

I did forget one thing. If the PPE request was based off of an interpretation of the LRM, chapter 10 (WPS language), I would clarify that this product is not for occupational use, just residential. Chapter 10 states that registrants may need to clarify that their product is not for general agricultural use (page 10-4). Therefore, I am adding the following claim to the label to alleviate this concern, which is modeled off of the simpler examples the LRM provides. This is standard language we have been adding to our consumer labels as we update them.

"For [outdoor] residential use [only]"

-Ian

From: Ian Murphy
Sent: Wednesday, April 14, 2021 11:04 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Thank you, Lydia.

I have a question about the request to add "Wear long-sleeved shirt and long pants, socks, shoes, and (waterproof or chemical-resistant) gloves" to the User Safety Recommendations.

I think this request could be driven by the Pendimethalin ID (EPA-HQ-OPP-2012-0219). It requested this language update to the handler precautionary statement for any end-use product. However, that ID also determined that "Residential handler activities do not represent risks of concern" with a MOE >20X safer than the Level of Concern in the worst case scenario (pages 9-10). With such a high safety factor, adding these statements seems unnecessary and potentially confusing to residential users.

Some Interim Decisions have differentiated residential/consumer label updates from commercial/ag updates to address similar situations. In those ID's, similar PPE statements were excluded for residential products. Diquat Dibromide ID, EPA-HQ-OPP-2009-0846, is an example: There were no residential handler risks for non-backpack applications (granules would be "non-backpack applied") and therefore it excluded PPE updates from residential products.

While each molecule is unique, perhaps the same conclusion of residential risk can lead the same application of mitigations and it could be appropriate to **not add** the PPE statement requested. It will not increase the risk to the consumer in the use of this product, according to the EPA's previous analysis.

Please let me know what you hear from the tox reviewers related to this, but I would prefer to not add this new PPE statement. In the meantime, I am working to add the other requested language.

Ian Murphy
Federal Registrations Manager

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From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Tuesday, April 13, 2021 3:12 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG/71995-63

Thanks, Ian. Here's an updated set of label comments addressing the tox report. I'm waiting on the chem report but I think we'll be okay on time.

Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Thursday, April 8, 2021 9:19 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG/71995-63

Lydia, Here is the updated label (base and highlighted version).

Ian Murphy
Federal Registrations Manager

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From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Wednesday, April 7, 2021 11:20 AM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG

Hi Ian,
Yes, those changes sound appropriate. Thanks for checking in on it.
Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Wednesday, April 7, 2021 11:17 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Morning, Lydia.

I imagine you have a lot on your plate, but wanted ask if the proposals I sent yesterday would be acceptable for this label.

If I don't hear back from you today, I will update my draft with the language as proposed and send back to you to keep things moving. If anything doesn't seem workable, please let me know. Thanks!

Ian

From: Ian Murphy
Sent: Tuesday, April 6, 2021 9:06 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Lydia,

Thank you for the discussion yesterday. I took a look at two Monsanto Lawn & Garden labels that were recently approved to see how they handled these issues (71995-25 and 71995-29, both approved in Jan, 2021. 71995-25 attached). Let me know if the proposals I list are acceptable.

- 1) "Insert graphics" language: They stated "insert graphic representing claim". (page 1 of label, page 3 of pdf file)
 - a. I propose to update bracketed statement to say "Insert Graphic Representing Claim"
- 2) "Insert brand name" language: They used [Insert brand name of 71995-xx] in first instance after page 1, then [insert brand name] was used for the rest of the label. (look at "Did You Know", page 4 of pdf file and compare to "How It Works", page 5 of pdf and rest of label)
 - a. I propose to do the same: page 7 of label will have "Insert brand name of 71995-63", and all others will stay as "Insert brand name" .
- 3) Bracketed Address: They had a similar approach to the address as 71995-63 currently does, but **they do** have an address outside of brackets. (page 12 of label, page 14 of pdf file)
 - a. I will remove the brackets that are around the address currently listed.

Ian

From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Monday, April 5, 2021 3:58 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG

Hi Ian,
Please see the attached label comments for 71995-AG.
Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Thursday, March 25, 2021 12:02 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Lydia, Here is the updated label (71995-63; base and highlighted) + your commented version (71995-AG_EPA Review_02242021) with my responses.
Please let me know if you have further comments or requests

Ian Murphy
Federal Registrations Manager

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From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Wednesday, March 10, 2021 2:13 PM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG

Good afternoon Ian,
As I said last time, I'm still waiting on the tox and chem reviews, so there will likely be more comments, but here is the first round of label review for this product.
Best,
Lydia

From: Crawford, Lydia
Sent: Tuesday, March 9, 2021 9:03 AM
To: 'Ian Murphy' <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG

Good morning Ian,
I have received your labels. I'm still waiting on the chemistry and toxicology reviews on this product, but I will be starting my label review this week.
Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Tuesday, March 9, 2021 8:42 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Morning, Lydia.

I wanted to confirm that you got my updated label, and see if there is any update on this petition. Does it seem like this will be reviewed soon?

While a PRIA date of April 28 feels far away to me, I imagine this needs to be reviewed soon in order to facilitate that date (optimistically assuming no issues are found that cannot be resolved quickly, of course).

Let me know. Thank you, and have a good day.

Ian Murphy
Federal Registrations Manager

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From: Ian Murphy
Sent: Thursday, February 25, 2021 4:03 PM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Lydia.

The updated label is attached, with the ABN on page 1.

Thank you for your flexibility on this.

Ian Murphy
Federal Registrations Manager

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From: Crawford, Lydia <Crawford.Lydia@epa.gov>
Sent: Monday, February 8, 2021 10:13 AM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status on pending 71995-AG

Hi Ian,

Yes, you can send the label with an updated ABN directly to me. I haven't started the label review yet, so that's not a problem at all.

Best,
Lydia

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Monday, February 8, 2021 9:11 AM
To: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status on pending 71995-AG

Good morning, Lydia,

I hope you are doing well. There has been some recent discussions on adding an ABN to 71995-AG. As this product is still in review, is possible for me to add an ABN while you are reviewing (send in an updated label with the ABN added, perhaps).

I realize normally this could be a separate notification, but I am concerned if I wait until after this renegotiated action timeline to notify, there is little chance this product could make it through most state reviews for a 2022 launch. Nor I am sure if I could submit a notification on a not-yet-registered product (would it make it through the front desk).

Let me know if sending in an ABN directly to you for review with the current action is possible. Thank you.

Ian Murphy
Federal Registrations Manager

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From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, January 25, 2021 6:42 AM
To: Ian Murphy <ian.murphy@bayer.com>
Cc: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status update on pending 71995 company actions

Hi Ian,

Mike went back and approved this one so the renegotiated PRIA date is 4/28/2021.

Best regards,
Emily

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Thursday, January 14, 2021 9:06 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status update on pending 71995 company actions

Emily,

Thank you for the update. Yes, I hope it can be delivered by/before that new date. Fortunately, since this is a "Me-too" action, the data and a similar label have been approved previously.

Curious if you can share more details about what does that denial meant. That management wants this done earlier than the date? Or later than what we discussed? Or neither?

Let me know, and continue to reach out as you have questions.

Ian Murphy
Federal Registrations Manager

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From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Thursday, January 14, 2021 8:55 AM
To: Ian Murphy <ian.murphy@bayer.com>
Cc: Crawford, Lydia <Crawford.Lydia@epa.gov>
Subject: RE: Status update on pending 71995 company actions

Hi Ian,

I just wanted to let you know that my request to renegotiate the PRIA date was denied by management. However, it finally passed the screen yesterday and I assigned it to Lydia. She let me know she would still treat it as if the PRIA date is the April date so hopefully it will still get done by then.

Let me know if you have any questions.

Best regards,
Emily

From: Schmid, Emily
Sent: Tuesday, January 12, 2021 11:03 AM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: FW: Status update on pending 71995 company actions

Thanks Ian!

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Tuesday, January 12, 2021 9:35 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Subject: RE: Status update on pending 71995 company actions

Emily,

Bayer authorizes the renegotiation of the PRIA due date to April 28, 2021 for the following product.
File symbol: 71995-AG
Decision number: 565186

Product name: Roundup® Landscape Weed Preventer

Bayer appreciates any effort the EPA can make to complete this review in advance of this renegotiated timeline. Thank you.

Ian Murphy
Federal Registrations Manager

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Web: <http://www.bayer.com>

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Monday, January 11, 2021 10:31 AM
To: Ian Murphy <ian.murphy@bayer.com>
Subject: RE: Status update on pending 71995 company actions

Hi Ian,

I wanted to check in with you about 71995-AG. I'd really like to get this renegotiated as soon as possible. Once PRIA actions have fallen off the PRIA clock, it makes it more difficult to get them worked on. Additionally, it can be difficult getting management to approve renegotiations after the PRIA date has passed so I'd like to address this as soon as possible.

Let me know if you have any questions.

Thanks,
Emily

From: Schmid, Emily
Sent: Wednesday, January 06, 2021 11:50 AM
To: Ian Murphy <ian.murphy@bayer.com>
Cc: Gerber, Theresa <Gerber.Theresa@epa.gov>; Holt, Aleah <Holt.Aleah@epa.gov>
Subject: RE: Status update on pending 71995 company actions

Hi Ian,

Happy New Year to you!

Theresa has been busy with a bunch of PRIA actions but thinks she should have some time open up in the next couple of weeks where she should be able to get back to 71995-25 and -29.

71995-40 and -49 have not been assigned to reviewers yet. As you know, we have been dealing with a massive backlog and haven't gotten to actions that were submitted last month yet.

I'm glad you brought 71995-AG to my attention again since it has passed the PRIA date. It still hasn't passed the front end screen (still backed up due to covid as I mentioned in my email a few weeks ago). I doubt it is because of a deficiency or the contractors would have been in touch with you. I was just notified of a few that passed the screen that came in the week before this one, so hopefully we won't have to wait too much longer for it to pass. In the meantime, we should get it renegotiated. Since this will have to go in for product chemistry and acute toxicity reviews, I don't see

how we can make your requested March date. I recommend we renegotiate this for four months (the PRIA timeline). If you are agreeable to this, please send me an email authorizing the renegotiation to April 28, 2021 and include the file symbol (71995-AG), decision number (565186) and product name.

Sorry I don't have better news for you. It's difficult times for RD. We really appreciate your understanding and patience.

Best regards,
Emily

From: Ian Murphy <ian.murphy@bayer.com>
Sent: Tuesday, January 05, 2021 4:46 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Gerber, Theresa <Gerber.Theresa@epa.gov>; Holt, Aleah <Holt.Aleah@epa.gov>
Subject: Status update on pending 71995 company actions

Happy New Year, Emily.

As 2021 begins, I am trying to get a status on various actions that are at the agency. If you can provide an update for the actions below, that would be greatly appreciated.

This doesn't list all actions in your team, but these are the most critical needs to our business.

EPA Reg #	Action	Additional info	Latest status	EPA's Update or Estimated time of completion?
71995-25	Label Amendment (Sept, 2018)	Enabling a new bottle type, as old bottle production has halted	Responded to reviewers June comments on 9/4; provided requested graphics on 11/24	
71995-29	Label Amendment (Aug, 2019) CDX_2019_006852	See above.	Responded to reviewers June comments on 9/4; provided requested graphics on 11/24	
71995-40	Label Amendment (Dec, 2020) EPA receipt: 1061543	See above. Updates the same or VERY similar to 71995-25 & 71995-29 updates, in case single reviewer could review all.	EPA provided comments in notification rejection (Oct, 2020), which Bayer addressed in label submitted in Dec.	
71995-49	Label Amendment (Dec, 2020) EPA receipt: 1061317	See above. Updates the same or VERY similar to 71995-25 & 71995-29 updates.	EPA provided comments in notification rejection (Oct, 2020), which Bayer addressed in label submitted in Dec.	
71995-AG	PRIA action (Aug, 2020) Decision 565186	PRIA date: 12/28/2020 R300 – 4 month timeline	PRIA time has passed. 12/14: Emily stated it hadn't cleared screening. Is there a deficiency?	Is it possible this could be reviewed/approved by mid-March, 2021?

Thanks, and feel free to call if you prefer to discuss.

Ian Murphy
Federal Registrations Manager

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